DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 20, 2015

Exactech, Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 North West 66th Court
Gainesville, Florida 32653

Re: K150066
Trade/Device Name: Exactech Alteon Monobloc Revision Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: May 28, 2015
Received: May 29, 2015

Dear Mr. Patrick Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150066

Device Name

Exactech Alteon Monobloc Revision Stem

Indications for Use *(Describe)*

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exactech® Alteon™ Monobloc Revision Stem
Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

Sponsor: Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 327-4762
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: Patrick Hughes
Senior Regulatory Affairs Specialist

Date: January 12, 2015

Trade of Proprietary or Model Name(s):
Exactech® Alteon™ Monobloc Revision Stem

Common Name:
Total Hip Arthroplasty – Femoral Components

Classification Name:
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Class II, Product Code LZO)

Information on devices to which substantial equivalence is claimed:

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
K043356	Wagner SL Revision Stem	Zimmer

Exactech® Alteon™ Monobloc Revision Stem
Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

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Device Description:
The Alteon Monobloc Revision Femoral Stem is a distally tapered, press-fit prosthesis featuring a 12/14 trunnion that is used on the femur side of a total or hemi hip arthroplasty. The Alteon Monobloc Revision Stem system is intended to treat typical Total Hip Arthroplasty primary and revision cases. Alteon Monobloc Revision Stem implants are made from titanium alloy and offer multiple stem lengths, offsets, and diameters to accommodate an array of patient anatomies.

Testing:
This submission includes results for the following non-clinical testing:

- Fatigue testing
- Range of motion analysis
- Cadaveric implantation and surgeon assessment
- Biocompatibility assessment

Substantial Equivalence Conclusion:
Results of engineering studies and comparison of key features included in this submission demonstrate the proposed Alteon Monobloc Revision Stem devices are substantially equivalent to cleared predicate Zimmer Wagner SL Revision Stem devices.